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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,097	03/11/2004	Fredrik Nilsson	12578/46202	6060

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EXAMINER	
STEELE, AMBER D	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/798,097	NILSSON, FREDRIK	
	Examiner	Art Unit	
	Amber D. Steele	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37,40-43,45,46,48 and 49* is/are pending in the application.

4a) Of the above claim(s) *12,15,16,19,20,28-37,40-43,45,46,48 and 49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13,14,17,18 and 21-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *March 11, 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/13/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-37, 40-43, 45-46, and 48-49 are currently pending.

Claims 38-39, 44, and 47 were canceled in the amendment to the claims received on February 15, 2006.

Claims 1-11, 13-14, 17-18, and 21-27 are currently under consideration.

Election/Restrictions

2. Applicant's election with traverse of Group V (claims 1-27) in the reply filed on February 15, 2006 is acknowledged. The traversal is on the ground that a serious burden does not exist. This is not found persuasive because the inventions of Groups I-X are drawn to various products, apparatus, and methods with different class and/or subclass designations, require different reagents, produce different products, are structurally different, and/or have different uses or different methods of making. Therefore, a search burden does exist.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 28-37, 40-43, 45-46, and 48-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 15, 2006.

4. Applicant's election with traverse of antibody as the species of binding molecules, at least about 10 different types of binding molecules as the species of number of binding molecules, C-terminal motif of four amino acids which comprises a C-terminal arginine or lysine and three additional variable amino acids as the species of motif, at least 10% at the species of capture, containing plasma proteins as the species of heterogenous sample, trypsin digestion as the species of fragmenting, desorption mass spectrometry as the species of characterizing, and collision induced mass spectrometry as the species of identifying in the reply filed on February 15, 2006 is acknowledged. The traversal is on the ground(s) that due to the election of antibody as the species of binding molecule, the requirement for an election of motif should be withdrawn since the specificity of the antibody will determine the motif. This is not found persuasive because the election of antibody while fulfilling the species requirement for a binding molecule represents a large subgenus of proteins that can bind to a large genus of antigens/epitopes. The elected species of antibody provides no structural regarding the binding pocket for the motif, therefore, a species of motif is required. However, upon further reconsideration the species requirement for (B) number of binding molecules, (E) heterogenous sample, (F) fragmenting, (G) characterizing, and (H) identifying are withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

5. Claims 12, 15-16, and 19-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 15, 2006.

Drawings

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Figures 2-14 are described together. Each figure should be described separately. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or **amendment to the specification to add the figure legend in the description** in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

7. The disclosure is objected to because of the following informalities: On page 39, line 18 M@LDI appears to be a typographical error. MALDI is suggested.

Appropriate correction is required.

Claim Interpretation

8. The presently claimed invention is directed to:

A method comprising:

(a) separating a heterogenous sample of proteins, peptides, or fragments into classes by wherein the members of each class have a motif common to the class and each class is spaced apart in a defined location on an array, and

(b) characterizing the proteins, peptides, or fragments in each class.

The limitation that the heterogenous sample is separated based on binding members is considered to be a functional limitation only.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-11, 13-14, 17-18, and 21-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because there is missing a nexus between method step (a) and method step (b). For example, if the heterogenous sample of proteins, peptides, or fragments can be separated into classes via a common motif then it would appear that the proteins, peptides, or fragments have already been characterized to an extent (e.g. via common motif). In addition, if the proteins, peptides, or fragments can be classified via binding members then it would appear that the proteins, peptides, or fragments have already been classified to an extent. Therefore, claim 1 and all its dependent claims are rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for

patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-11, 13-14, 17-18, 21-22, 25, and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Minden et al. WO 02/086081 A2 (filing date April 22, 2002).

For present claim 1, Minden et al. teach methods of identifying a protein via assigning (e.g. separating) binding reagents to designated locations on an array, detecting the binding patterns, and comparing the binding pattern to a reference set (e.g. characterizing; please refer to the abstract, paragraphs [0005-0012], [0028-0032], [0035-0044], [0072-0074], [0077], [00117], Figures 1-11, and Table 1).

For present claim 2, Minden et al. teach that the total protein content of a cell or tissue can be utilized as the protein mixture (please refer to paragraphs [0035], [0066]).

For present claims 3-6, Minden et al. teach that the protein mixture can be fragmented with various chemical or enzymatic methods including trypsin (please refer to paragraph [0037-0039], [0066], [00105], [00107], and Table 1).

For present claims 7-8 and 11, Minden et al. teach that trypsin cleavage forms a peptide or epitope (e.g. motif) with C-terminal lysine or arginine residues (please refer to Table 1 and paragraphs [0041-0045], [0049], [0054], [0063]).

For present claims 9-10, Minden et al. teach that the peptides or epitopes (e.g. motifs) can be at least three amino acids in length and can have at least two variable amino acids (please refer to paragraphs [0029], [0032], [0040-0046], [0054], [00113-00116]).

For present claim 13, Minden et al. teach that arrays can have different binding molecules at spatially addressable locations which bind to different binding reagents (please refer to paragraphs [0005], [0008], [0012], [0028], [0040]).

For present claim 14, Minden et al. teach that the protein mixture may comprise all (e.g. 100%) of the proteins and that the epitopes cover the binding mixture (please refer to paragraph [0035], [0040]).

For present claim 17, Minden et al. teach that the array can have 2-100 different proteins (please refer to paragraphs [0047], [0073-0074]).

For present claim 18, Minden et al. teach that the binding reagents can be antibodies (please refer to paragraphs [0029], [0056-0061], [0072]).

For present claim 21, Minden et al. teach that the proteins are compared to a reference set (e.g. characterizing; please refer to paragraphs [0005], [0028-0031], [0040]).

For present claim 22, Minden et al. teach that the molecular weight or mass of the binding reagents can be determined and that spectrometry can be utilized (please refer to paragraphs [0030], [0036], [0048]).

For present claim 25, Minden et al. teach that the reference set can include prediction about binding based on the predicted digests of a protein mixture (e.g. unfragmented; please refer to paragraph [0031]).

For present claim 27, Minden et al. teach that various binding reagents can be compared to a reference set or to other binding reagents (please refer to paragraphs [0005], [0030-0031, [0040], [0053]).

Therefore, one of skill in the art would have anticipated the presently claimed invention in view of the teachings of Minden et al.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 1-11, 13-14, 17-18, and 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minden et al. WO 02/086081 A2 (filing date April 22, 2002) and Barry et al. WO 0225287 (filed September 19, 2001).

For present claim 1, Minden et al. teach methods of identifying a protein via assigning (e.g. separating) binding reagents to designated locations on an array, detecting the binding patterns, and comparing the binding pattern to a reference set (e.g. characterizing; please refer to the abstract, paragraphs [0005-0012], [0028-0032], [0035-0044], [0072-0074], [0077], [00117], Figures 1-11, and Table 1).

For present claim 2, Minden et al. teach that the total protein content of a cell or tissue can be utilized as the protein mixture (please refer to paragraphs [0035], [0066]).

For present claims 3-6, Minden et al. teach that the protein mixture can be fragmented with various chemical or enzymatic methods including trypsin (please refer to paragraph [0037-0039], [0066], [00105], [00107], and Table 1).

For present claims 7-8 and 11, Minden et al. teach that trypsin cleavage forms a peptide or epitope (e.g. motif) with C-terminal lysine or arginine residues (please refer to Table 1 and paragraphs [0041-0045], [0049], [0054], [0063]).

For present claims 9-10, Minden et al. teach that the peptides or epitopes (e.g. motifs) can be at least three amino acids in length and can have at least two variable amino acids (please refer to paragraphs [0029], [0032], [0040-0046], [0054], [00113-00116]).

For present claim 13, Minden et al. teach that arrays can have different binding molecules at spatially addressable locations which bind to different binding reagents (please refer to paragraphs [0005], [0008], [0012], [0028], [0040]).

For present claim 14, Minden et al. teach that the protein mixture may comprise all (e.g. 100%) of the proteins and that the epitopes cover the binding mixture (please refer to paragraph [0035], [0040]).

For present claim 17, Minden et al. teach that the array can have 2-100 different proteins (please refer to paragraphs [0047], [0073-0074]).

For present claim 18, Minden et al. teach that the binding reagents can be antibodies (please refer to paragraphs [0029], [0056-0061], [0072]).

For present claim 21, Minden et al. teach that the proteins are compared to a reference set (e.g. characterizing; please refer to paragraphs [0005], [0028-0031], [0040]).

For present claim 22, Minden et al. teach that the molecular weight or mass of the binding reagents can be determined and that spectrometry can be utilized (please refer to paragraphs [0030], [0036], [0048]).

For present claim 25, Minden et al. teach that the reference set can include prediction about binding based on the predicted digests of a protein mixture (e.g. unfragmented; please refer to paragraph [0031]).

For present claim 27, Minden et al. teach that various binding reagents can be compared to a reference set or to other binding reagents (please refer to paragraphs [0005], [0030-0031, [0040], [0053]).

However, Minden et al. does not specifically teach determining the abundance of the proteins or the use of desorption mass spectrometry or collision induced dissociation mass spectrometry.

Barry et al. teach methods of determining the binding and mass of trypsin digested proteins (including antibodies) from a cell (including phage) or tissue sample immobilized on an array (please refer to the abstract, pages 2-6, 21-30, Figures 3-6 and 8-10, Examples 2-3).

For present claim 23, Barry et al. teach determining the abundance of proteins via MALDI-TOF (e.g. mass; please refer to pages 5-6, page 32, lines 25-33, page 33, lines 21-37, pages 34-35, Figures 3-6 and 8-10, Examples 2-3).

For present claim 24, Barry et al. teach MALDI-TOF (matrix assisted laser desorption ionization-time of flight) mass spectrometry (e.g. combination of both desorption mass spectrometry and collision induced dissociation mass spectrometry or CID page 35, line 7; please refer to pages 5-6, page 32, lines 25-33, page 33, lines 21-37, pages 34-35, Figures 3-6 and 8-10, Examples 2-3).

For present claim 26, Barry et al. teach determining the abundance of the protein (please refer to pages 5-6, page 32, lines 25-33, page 33, lines 21-37, pages 34-35, Figures 3-6 and 8-10, Examples 2-3).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of identifying proteins taught by Minden et al. with the MALDI-TOF analysis taught by Barry et al.

One having ordinary skill in the art would have been motivated to do this because Barry et al. teach that the use of mass spectrometry and MALDI-TOF provide semi-quantitative and quantitative results for protein microarrays (please refer to page 1, lines 20-26 and 34-37; page 2, lines 1-24; page 3, lines 5-30; Examples 2-3).

One of ordinary skill in the art would have had a reasonable expectation of success in the modification of the method of identifying proteins taught by Minden et al. with the MALDI-TOF analysis taught by Barry et al. because of the examples provided by Barry et al. showing that trypsin digested antibody arrays can be quantitated via MALDI-TOF (please refer to Examples 2-3).

Therefore, the modification of the method of identifying proteins taught by Minden et al. with the MALDI-TOF analysis taught by Barry et al. render the instant claims prima facie obvious.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ADS
May 3, 2006

PETER PARAS, JR.
PRIMARY EXAMINER
SPE1639